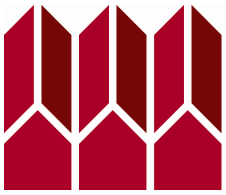

PEW COMMISSION ON
INDUSTRIAL FARM
ANIMAL PRODUCTION

Statement by Robert P. Martin, Executive Director
Pew Commission on Industrial Farm Animal Production
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Health Subcommittee of the House Energy and Commerce Committee

Good morning Mr. Chairman and members of the Health Subcommittee. My name is Robert P. Martin and I am the executive director of the Pew Commission on Industrial Farm Animal Production. I appreciate the opportunity to appear today.

The Pew Commission on Industrial Farm Animal Production (PCIFAP) is an independent commission funded by a grant from The Pew Charitable Trusts to the Johns Hopkins Bloomberg School of Public Health to investigate the problems associated with industrial farm animal production (IFAP) operations and to make recommendations to solve them. Fifteen Commissioners with diverse backgrounds began meeting in early 2006 to start their evidence-based review of the problems caused by IFAP.

Over the last two years, the Commission conducted 11 meetings and received thousands of pages of material submitted by a wide range of stakeholders and interested parties. Two public hearings were held to hear from the general public with an interest in IFAP issues. Eight technical reports were commissioned from leading academics to provide information in the Commission's areas of interest. The Commissioners themselves brought expertise in animal agriculture, public health, animal health, medicine, ethics, and rural sociology to the discussion.

In addition, the Commission visited broiler, hog, dairy, egg, and swine IFAP operations, as well as a large cattle feedlot.

The Commission's findings make clear that the present system of producing food animals in the United States is not sustainable and presents an unacceptable level of risk to public health, damage to the environment, as well as unnecessary harm to the animals we raise for food. In addition, the current system of industrial food animal production is detrimental to rural communities.

The Commission released its full report on April 29, 2008, that included 24 primary recommendations. The Commission was so concerned about the indiscriminate use of antibiotics in food animal production, and the potential threat to public health, that five of those recommendations deal with antibiotic use. Those recommendations follow.

Recommendation #1: **Restrict the use of antimicrobials in food animal production to reduce the risk of antimicrobial resistance to medically important antibiotics.**

a. Phase out and ban use of antimicrobials for non-therapeutic (i.e. growth promoting) use in food animals[1] (see PPCIFAP definition of "non-therapeutic").

b. Immediately ban any new approvals of antimicrobials for non-therapeutic uses in food animals[2] and retroactively investigate antimicrobials previously approved**.**

[1] The PCIFAP defines nontherapeutic as any use of antimicrobials in food animals in the absence of clinical disease or known (documented) disease exposure; i.e. any use of the drug as a food or water additive for **growth promotion**, feed efficiency, weight gain, disease prevention in the absence of documented exposure or any other "routine" use as non-therapeutic.

[2] The PCIFAP defines nontherapeutic as any use of antimicrobials in food animals in the absence of clinical disease or known (documented) disease exposure; i.e. any use of the drug as a food or water additive for **growth promotion**, feed efficiency, weight gain, disease prevention in the absence of documented exposure or any other "routine" use as non-therapeutic.

c. Strengthen recommendations in FDA Guidance #152 which requires the FDA determine that the drug is safe and effective for its intended use in the animal prior to approving an antimicrobial for a new animal drug application.

d. To facilitate reduction in IFAP use of antibiotics and educate producers on how to raise food animals without using nontherapeutic antibiotics, the USDA's extension service should be tasked to create and expand programs that teach producers the husbandry methods and best practices necessary to maintain the high level of efficiency and productivity they enjoy today.

Background

In 1986 Sweden banned the use of antibiotics in food animal production except for therapeutic purposes and Denmark followed suit in 1998. A WHO (2002) report on the ban in Denmark found that "the termination of antimicrobial growth promoters in Denmark has dramatically reduced the food animal reservoir of enterococci resistant to these growth promoters, and therefore reduced a reservoir of genetic determinants (resistance genes) that encode antimicrobial resistance to several clinically important antimicrobial agents in humans." The report also determined that the overall health of the animals (mainly swine) was not affected and the cost to producers was not significant. Effective January 1, 2006, the European Union also banned the use of growth-promoting antibiotics (Meatnews.com, 2005).

In 1998, the National Academy of Sciences (NAS) Institute of Medicine (IOM) noted that antibiotic-resistant bacteria increase U.S. health care costs by a minimum of $4 billion to $5 billion annually (IOM, 1998). A year later, the NAS estimated that eliminating the use of antimicrobials as feed additives would cost each American consumer less than $5 to $10 per year, significantly less than the additional health care costs attributable to antimicrobial resistance (NAS, 1999). In a 2007 analysis of the literature, another study found that a hospital

stay was $6,000 to $10,000 more expensive for a person infected with a resistant bacterium as opposed to an antibiotic-susceptible infection (Cosgrove *et al*, 2005). The American Medical Association, American Public Health Association, National Association of County and City Health Officials, and National Campaign for Sustainable Agriculture are among the more than 300 organizations representing health, consumer, agricultural, environmental, humane, and other interests supporting enactment of legislation to phase out nontherapeutic use in farm animals of medically important antibiotics and calling for an immediate ban on antibiotics vital to human health.

The Preservation of Antibiotics for Medical Treatment Act of 2007 (PAMTA) amends the Federal Food, Drug, and Cosmetic Act to withdraw approvals for feed-additive use of seven specific classes of antibiotics[3]—penicillins, tetracyclines, macrolides, lincosamides, streptogramins, aminoglycosides, and sulfonamides—each of which contains antibiotics also used in human medicine (2007a). The PAMTA provides for the automatic and immediate restriction of any other antibiotic used only in animals if the drug becomes important in human medicine, unless FDA determines that such use will not contribute to the development of resistance in microbes that have the potential to affect humans. FDA Guidance #152 defines an antibiotic as potentially important in human medicine if FDA issues an Investigational New Drug determination or receives a New Drug Application for the compound (2007a).

Most antibiotics currently used in animal production systems for nontherapeutic purposes were approved before the Food and Drug Administration (FDA) began giving in-depth consideration

[3] Fluoroquinolones are approved in animals only for therapeutic use (not for nontherapeutic use), and thus are not covered under PAMTA.

to resistance during the drug approval process. The FDA has not established a schedule for reviewing existing approvals, although Guidance #152 notes the importance of doing so. Specifically, Guidance #152 sets forth the responsibility of the FDA Center for Veterinary Medicine (CVM), which is charged with regulating antimicrobials approved for use in animals: "prior to approving an antimicrobial new animal drug application, FDA must determine that the drug is safe and effective for its intended use in the animal. The Agency must also determine that the antimicrobial new animal drug intended for use in food-producing animals is safe with regard to human health (FDA-CVM, 2003)." The Guidance also says that "the FDA believes that human exposure through the ingestion of antimicrobial-resistant bacteria from animal-derived foods represents the most significant pathway for human exposure to bacteria that have emerged or been selected as a consequence of antimicrobial drug use in animals." However, it goes on to warn that the "FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, the guidance describes the Agency's current thinking on the topic and should be viewed only as guidance, unless specific regulatory or statutory requirements are cited. The use of the word 'should' in Agency guidance means that something is suggested or recommended, but not required" (FDA-CVM, 2003).

The Commission believes that the "recommendations" in Guidance #152 should be made legally enforceable and applied retroactively to previously approved antimicrobials. Additional funding for FDA is required to achieve this recommendation.

Recommendation #2. **Clarify antimicrobial definitions to provide clear estimates of use and facilitate clear policies on antimicrobial use.**

a. The Commission defines as *non-therapeutic*[4] any use of antimicrobials in food animals in the absence of microbial disease or known (documented) microbial disease exposure; thus, any use of the drug as an additive for growth promotion, feed efficiency, weight gain, routine disease prevention in the absence of documented exposure, or other routine purpose is considered non-therapeutic.[5]
b. The Commission defines as *therapeutic* the use of antimicrobials in food animals with diagnosed microbial disease.
c. The Commission defines as *prophylactic* the use of antimicrobials in healthy animals in advance of an expected exposure to an infectious agent or after such an exposure but before onset of laboratory-confirmed clinical disease as determined by a licensed professional.

Background

In 2000 the WHO, United National Food and Agriculture Organization (FAO), and World Organization for Animal Health (OIE, *Fr.* Office International des Épizooties) agreed on definitions of antimicrobial use in animal agriculture based on a consensus (WHO 2000). Government agencies in the United States, including the USDA and FDA, govern aspects of antimicrobial use in food animals but have varying definitions of such use. Consistent definitions should be adopted for the use of all U.S. oversight groups that estimate types of antimicrobial use and for the development of law and policy. Congress recently revived a bill to address the antimicrobial resistance problem: the Preservation of Antibiotics for Medical Treatment Act of 2007 (PAMTA) defines non-therapeutic use as "any use of the drug as a feed or water additive for an animal in the absence of any clinical sign of disease in the animal for growth promotion, feed efficiency, weight gain, routine disease prevention, or other routine purpose (2007a)." If the

[4] For the Commission's recommendations, the members considered many definitions; a complete list of sources is in Appendix 1.

[5] This definition is adapted from PAMTA.

bill becomes law, this will be the legal definition of non-therapeutic use for all executive agencies and therefore legally enforceable.

Recommendation #3. **Improve monitoring and reporting of antimicrobial use in food animal production in order to accurately assess the quantity and methods of antimicrobial use in animal agriculture.**

a. Require pharmaceutical companies that sell antimicrobials for use in food animals to provide a calendar-year annual report of the quantity sold. Companies currently report antibiotic sales data on an annual basis from the date of the drug's approval, which makes data integration difficult. The FDA is responsible for oversight of the use of antimicrobials in food animals and needs consistent data on which to report use.
b. Require reporting of antimicrobial use in food animal production, including antimicrobials added to food and water, and incorporate the reported data in the USDA's National Animal Identification System (NAIS).[6] The FDA CVM regulates feed additives but does not have the budget or personnel to oversee their disposition after purchase. In addition, CVM and USDA are responsible for monitoring the use of prescribed antimicrobials in livestock production, but rely on producers and veterinarians to keep records of the antibiotics used and for what purpose.
c. Institute better integration, monitoring, and oversight by government agencies by developing a comprehensive plan to monitor antimicrobial use in food animals, as called for in a 1999 National Research Council (NRC) report (NAS, 1999). An integrated national database of antimicrobial resistance data and research would greatly improve the organization, amount, and types of data collected and would facilitate necessary policy changes by increasing data cohesion and accuracy. Further, priority should be given to linking data on both antimicrobial

[6] The USDA APHIS has begun implementing an animal tracking system, the National Animal Identification System (NAIS; http://animalid.aphis.usda.gov/nais/index.shtml). Announced in May 2005, the NAIS tracks both premises and 27 species of food animals (including cattle, goats, sheep, swine, poultry, deer, and elk). The data are linked to several databases run by private technology companies, while the USDA shops for a technology company with data warehousing expertise to run the full national database. The United Kingdom uses a similar database system for its Cattle Tracing System (CTS; http://www.bcms.gov.uk/), which facilitates tracking and is accessible online to users and administrators. See PCIFAP Recommendation #6 in this section for more information.

use and resistance in the National Antimicrobial Resistance Monitoring System (NARMS). This could be accomplished by full implementation of Priority Action 5 of *A Public Health Action Plan to Combat Antimicrobial Resistance,* which calls for the establishment of a monitoring system and the assessment of ways to collect and protect the confidentiality of usage data ((CDC/FDA/NIH, 1999). Since the USDA already provides antimicrobial use data in fruit and vegetable production it seems logical that usage information can be obtained from either agriculture producers and/or the pharmaceutical industry without undue burden.

Background

There are no reliable data on antimicrobial use in U.S. food animal production. Rather, various groups have reported estimates of use based on inconsistent standards. For example, in 2001 the Union of Concerned Scientists (UCS) estimated that 24.6 million pounds of antimicrobials were used per year for non-therapeutic purposes (Mellon *et al*, 2001) in animal agriculture (only cattle, swine, and poultry), whereas the Animal Health Institute (AHI) figure for the same year was only 21.8 million pounds for *all* animals and uses (therapeutic and non-therapeutic) (AHI, 2002). These disparities make it difficult to get a true picture of the state and extent of antimicrobial use and its relationship to antimicrobial resistance in industrial farm animal production.

Recommendation #4. **Improve monitoring and surveillance of antimicrobial resistance in the food supply, the environment, and animal and human populations in order to refine knowledge of antimicrobial resistance and its impacts on human health.**

a. Integrate, expand, and increase the funding for current monitoring programs.
b. Establish a permanent interdisciplinary oversight group with protection from political pressure, as recommended in the 1999 NRC report *The Use of Drugs in Food Animals: Risks and Benefits*. The group members should represent agencies involved in food animal drug regulation (e.g., the FDA, CDC, USDA), similar to the Interagency Task Force (CDC/FDA/NIH, 1999). In order to gather useful national data on antimicrobial resistance in the United States, the group should review progress on data collection and reporting, and

should coordinate both the organisms tested and the regions where testing is concentrated, in order to better integrate the data. Agency members should coordinate with each other and with the NAIS to produce an annual report that includes integrated data on human and animal antimicrobial use and resistance by region. Finally, the group should receive appropriate funding from Congress to ensure transparency in funding as well as scientific independence.

c. Revise existing programs and develop a comprehensive plan to incorporate monitoring of the farm environment (soils and plants) and nearby water supplies with the monitoring of organisms in farm animals.
d. Improve testing and tracking of antimicrobial-resistant infections in health care settings. Better tracking of AMR infections will give health professionals and policymakers a clearer picture of the role of antimicrobial-resistant organisms in animal and human health and will support more effective decisions about the use of antimicrobials.

Background

Monitoring and surveillance of antimicrobial resistance in the United States are covered by the National Antimicrobial Resistance Monitoring System (NARMS), a program run by FDA in collaboration with CDC and USDA. CDC is responsible for monitoring resistance in humans, but other federal agencies also conduct antimicrobial resistance research activities. For instance, the USDA National Animal Health Monitoring System (NAHMS) compiles food animal population statistics, animal health indicators, and antimicrobial resistance data. The USDA Collaboration in Animal Health and Food Safety Epidemiology (CAHFSE) is a joint effort of the department's Animal and Plant Health Inspection Service (APHIS), Agricultural Research Service (ARS), and Food Safety and Inspection Service (FSIS) to monitor bacteria that pose a food safety risk, including AMR bacteria. The USGS studies the spread of antimicrobial-resistant organisms in the environment. To achieve a comprehensive plan for monitoring and responding to antimicrobial resistance in the food supply, the environment, and animal and human populations, these agencies should work together to create an integrated plan with independent

oversight, and should upgrade from a passive form of monitoring to an active, comprehensive, uniform, mandatory approach.

The U.S. and state geological surveys (Krapac, 2004; USGS, 2006) as well as several independent groups (Batt, Snow et al. 2006; Centner 2006; Peak, Knapp et al. 2007) have looked closely at the spread of antimicrobial-resistant organisms in the environment, specifically in waterways, presumably from runoff or flooding. A recent study by the University of Georgia suggested that even chickens raised without exposure to antibiotics were populated with resistant bacteria. The authors suggested that an incomplete cleaning of the farm environment could have allowed resistant bacteria to persist and re-infect naïve hosts (Idris, Lu et al. 2006; Smith, Drum et al. 2007). In Denmark, it took several years after the withdrawal of antimicrobials for antimicrobial resistance to diminish in farm animal populations. These experiences emphasize the importance of monitoring the environment for antimicrobial contamination and responding with careful and comprehensive planning.

Recommendation #5. **Increase veterinary oversight of all antimicrobial use in food animal production, to prevent overuse and misuse of antimicrobials.**

a. Restrict public access to agricultural sources of antimicrobials.
b. Enforce restricted access to prescription drugs. By law, only a veterinarian may order the extra-label use of a prescribed drug in animals, but in fact prescription drugs are widely available for purchase online, directly from the distributors or pharmaceutical companies, or in feed supply stores without a prescription. Without stricter requirements on the purchase of antimicrobials, extra-label (i.e., non-therapeutic) use of these drugs is possible and even probable. For that reason, *no* antibiotics should be available for over-the-counter purchase.
c. Enforce veterinary oversight and authorization of all decisions to use antimicrobials in food animal production. The extra-label drug use (ELDU) rule under the Animal Medicinal Drug

Use Clarification Act (AMDUCA) permits veterinarians to go beyond label directions in using animal drugs and to use legally obtained human drugs in animals. However, the rule does not permit ELDU in animal feed or to enhance production. ELDU is limited to cases in which the health of the animal is threatened or in which suffering or death may result from lack of treatment. Veterinarians should consider ELDU in food-producing animals only when no approved drug is available that has the same active ingredient in the required dosage form and concentration or that is clinically effective for the intended use (1994). North Carolina State University, the University of California-Davis, and the University of Florida run the Food Animal Residue Avoidance Databank (FARAD) (http://www.farad.org/), which includes useful information for food animal veterinarians, including vetGRAM, which lists label information for all food animal drugs. To be effective, AMDUCA and ELDU must be enforced. In addition, the FDA CVM should compel veterinarians to submit prescription and treatment information on farm animals to a national database to allow better tracking of antibiotic use as well as better oversight by veterinarians, as technology allows. Veterinary education for food animal production should teach prescription laws and reporting requirements.

d. Encourage veterinary consultation in these decisions.
e. AMDUCA requires the veterinarian to properly label drugs used in a manner inconsistent with the labeling (i.e., extra-label) and to give the livestock owner complete instructions about proper use of the drug. Further, ELDU must take place in the context of a valid, current veterinarian-client-patient relationship—the veterinarian must have sufficient knowledge of the animal to make a preliminary diagnosis that will determine the intended use of the drugs. The producer should be encouraged to work with the veterinarian both to ensure the health of the animal(s) and to conform to antibiotic requirements. For example, the National Pork Board Pork Quality Assurance program encourages consultation with veterinarians to maintain a comprehensive herd health program (NPB, 2005).

Background

Presenters at a 2003 NRC workshop concluded that unlike human use of antibiotics, non-therapeutic uses in animals typically do not require a prescription (certain antimicrobials are sold over the counter and widely used for purposes or administered in ways not described on the label) (Anderson *et al*, 2003). After the passage of AMDUCA, veterinarians gained the right to

prescribe/dispense drugs for "extra-label" use but the FDA limits such use to protect public health (1994), (before AMDUCA, veterinarians were not legally permitted to use an animal drug in any way except as indicated on the label). ELDU occurs when the drug's actual or intended use is not in accordance with the approved labeling. For instance, ELDU refers to administration of a drug for a species not listed on the label; for an indication, disease, or other condition not on the label; at a dosage level or frequency not on the label; or by a route of administration not on the label. Over-the-counter sale of antimicrobials opens the door to the non-therapeutic, unregulated use of antibiotics in farm animals.

The issues being considered today by this Subcommittee are of great concern to the members of the Pew Commission, the medical community, and the veterinary community. The members of the Pew Commission look forward to working with you as you continue consideration of this very important issue. Mr. Chairman and members of the Subcommittee, thank you again for allowing me to testify.